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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,737	11/25/2003	Bradley S. Galer	BSG 021 US	7300

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EXAMINER

GEORGE, KONATA M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/722,737	Applicant(s) GALER, BRADLEY S.	
	Examiner Konata M. George	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/30/04; 6/21/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-11 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on April 30, 2004 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement, except for the following document: US Patent No. 5,668,830. US Patent No. 5,668,830 is drawn to a "Digital Phase Alignment and Integrated Multichannel Transceiver..." which is not related to the claimed invention.

The information disclosure statement filed June 21, 2004 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Forrest (US 4,963,345) as evidenced by Hawley's Condensed Chemical Dictionary, 1997.

Column 1, lines 63-66 teach the present disclosure is a pharmaceutical, which rapidly reverses or counteracts the effect of the local anesthetic. Hawley's Condensed Chemical Dictionary describes an anesthetic as a chemical compound that induces loss of sensation in a specific part or all of the body. Applicant describes neuropathic negative sensory phenomena as numbness or decreased sensation (spec. paragraph 0002). Therefore, since the prior art teaches a method of reverses or counteracting the effects of a local anesthetic (loss of sensation), then the prior art anticipates claims 1 and 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1616

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al. (US 5,028,435) in view of Goodman and Gilman's (The Pharmacological Basis of Therapeutics).

Applicant claims a method for treating neuropathic negative sensory phenomena comprising applying an anesthetic to a patient. The anesthetic can be a benzoic acid derivative such as lidocaine, cocaine, etc. and is delivery via a patch.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Katz et al. discloses a system and method for delivery for transdermal drug delivery. The system comprises a matrix layer having a backing or enclosure, wherein the matrix layer contains a drug (col. 2, lines 58-60). Column 5, lines 43-55 teach exemplary drugs which may be delivered by the system of which anesthetics are disclosed (lines 44-45). Figure 1, discloses a system comprising a backing layer and a matrix layer containing the drug (as a solid or liquid) and polymeric beads (col. 11, lines

Art Unit: 1616

55-65). Column 5, lines 23-34 teach that the matrix layer can be made from polyvinyl chlorides, silicon rubbers, etc.

Goodman and Gilman's teach examples of local anesthetics such as lidocaine, dibucaine, etc. It is taught that lidocaine can be prepared as an ointment, jelly or topical solution (See Preparations, page 320). It is also taught that market preparations contain 0.5 to 20% and topical mucosal compositions 1 to 5%.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

The prior art of Katz et al. does not teach the specific anesthetic as claimed by applicant or the weight percent of the drug in the patch.

Finding of prima facie obviousness

Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Goodman and Gilman's that lidocaine can be administered topically as an anesthetic in the system of Katz et al. which discloses a transdermal system which can comprise anesthetics to disclose the invention as claimed. Although it is not explicitly disclosed, administering the system near the locus of the negative sensory phenomena would be within the skill of the ordinary worker as part of the process of normal optimization to achieve the desired results of the claimed method.

Art Unit: 1616

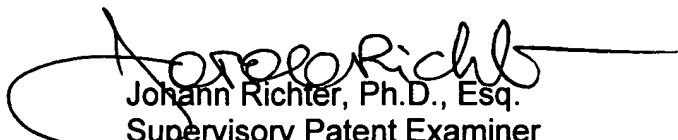
Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) as 866-217-9197 (toll-free).

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